

REMARKS

Claims 1-83 were pending. Claim 1 has been amended to correct an obvious editorial error. Claims 25, 38, 56, 57, 71, 72, 73, and 74 have been amended to correct multiple dependencies. New claims 84-91 mirror claims 25, 38, 56, 57, and 71-74, and have been added to maintain dependencies removed from the claims amended to correct improper multiple dependencies. Claims 20-24 and 46-55 have been cancelled, without prejudice, as drawn to a non-elected invention. Accordingly, no new matter is introduced by these new claims or amendments.

Objections Under 37 C.F.R. §§ 1.821 to 1.825

The Examiner has indicated that the instant application fails to comply with the requirements of 37 C.F.R. §§ 1.821 to 1.825 for the reasons set forth in the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence And/or Amino Acid Sequence Disclosures (“Notice”). In particular, the Notice indicates that the application does not contain, as a separate part of the disclosure on paper copy, a “Sequence Listing” as required by 37 C.F.R. § 1.821(c) and that a copy of the “Sequence Listing” in computer readable form has not been submitted as required by 37 C.F.R. § 1.821(e).

In response, Applicants submit as Exhibit A, a copy of the return receipt postcard bearing the stamp of the United States Patent and Trademark Office indicating that a Sequence Listing in both paper and computer readable form was received on January 9, 2004. Nevertheless, in order to be fully responsive Applicants submit herewith a Substitute Sequence Listing in paper and computer readable form in accordance with the Notice and have requested that the Substitute Sequence Listing be entered into the specification.

The Examiner has also noted that claims 47-55 recite a 15 amino acid sequence AVITAG and contends that the sequence fails to comply with the Sequence Rules.

In response, Applicants submit that 37 C.F.R. §§ 1.821-1.825 applies only where nucleotide and/or amino acid sequences are disclosed in the application. In the instant application, the *sequence* of the AVITAG is not disclosed and thus is not required to be part of the Sequence Listing. Moreover, at the time of filing of the instant application, the AVITAG sequence was a microbiological tool known in the art, used to allow the biotinylation of proteins (*see, e.g.*, Schatz, 1993, Biotechnology, 11:1138-1143, and U.S. Patent No. 5,723,584).

Objections to the Claims

The Examiner has indicated that claim 25 and many other claims are improper multiply dependent claims. In response, as discussed above, applicants have amended claims 25, 38, 46, 56, 57, and 71-74 to remove improper dependencies. Applicants have further added new claims 84-94 to maintain the dependencies of the originally filed claims.

Election/Restrictions

The Examiner has required a restriction to one of the following inventions under 35 U.S.C. § 121:

- I. Claims 1-19, 25-30, 37-41, and 67-83, drawn to a polypeptide and a composition comprising a variant Fc region, classified in Class 530, subclass 387.3; Class 424, subclass 130.1.
- II. Claims 20-24 and 42-46, drawn to a nucleic acid encoding a polypeptide comprising a variant Fc region, a vector, a host cell, and a method of recombinantly producing the antibody, classified in Class 536, subclass 23.1; Class 435, subclasses 69.9 and 326.
- III. Claims 47, 51-55, drawn to a method for producing a tetrameric Fc γ R complex, classified in Class 530, subclass 350.
- IV. Claims 48-50, drawn to a tetrameric Fc γ R complex, classified in Class 435, subclass 69.1.
- V. Claims 31-36 and 56-66, drawn to a method of treating a patient by administering an antibody, classified in Class 424, subclass 141.1.

The Examiner contends that the inventions are distinct, each from the other.

Applicants hereby provisionally elect, Group I, Claims 1-19, 25-30, 37-41, and 67-83, drawn to a polypeptide and a composition comprising a variant Fc region. Applicants further submit that newly added claims 84-85 and 88-91 fall within the subject matter of elected Group I.

In addition to election of one of the above inventions, the Examiner required election of one specific polypeptide comprising a variant Fc region, wherein the Fc region is described by election from the following genera:

Genus 1: a specific IgG isotype;
Genus 2: a specific one amino acid substitution at a specific position;
Genus 3: applicable functional limitations encompassed by the elected antibody species; and
Genus 4: binds a specific antigen.

Additionally, the Examiner required election of one of the following species of composition in the event that Group I or Group V is elected:

Species 1: without additional agent;
Species 2: with additional agent.

The Examiner also required election of a species of disease to be treated in the event that Group V is elected.

Applicants hereby provisionally elect from Genus 1, IgG1; from Genus 2, Leu at position 396; from Genus 3, binds Fc γ RIIIA with greater affinity; and from Genus 4, specifically binds HER2/neu. With respect to the composition, Applicants hereby provisionally elect Species 1: without additional agent. Applicants respectfully submit that the election of Group I renders the species election of Group V moot.

Applicants believe that the claims within elected Group I that are readable upon the elected species are as follows:

IgG1: Claims 1-19, 25-30, 37-41, 67-85, 88-91;
396L: Claims 1-5, 8-9, 12, 15-19, 25-30, 37-41, 67-82, 84-85, and 88-91;
Fc γ RIIIA with greater affinity: Claims 1-19, 25-30, 37-41, 67-85, 88-91;
Her2/neu: Claims 1-19, 25-30, 37-41, 67-85, 88-91;
without additional agent: Claims 1-19, 25-30, 37-39, 67-85, 88-91.

Applicants note that should a generic claim be allowed, Applicants will be entitled to consideration of claims to additional species that are written in dependent form or otherwise include all limitations of an allowed generic claim pursuant to 37 C.F.R. § 1.141.

Upon the allowance of a product claim, Applicants request that any withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim be rejoined in accordance with the provisions of M.P.E.P. § 821.04. Presently, Applicants believe that the process claims 31-36, 56-66 and 86-87 include all the limitations of a pending product claim within elected Group I.

Applicants fully reserve the right to prosecute the subject matter of the non-elected inventions in one or more related applications. In addition, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully request that the above remarks be entered and made of record in the file history of the instant application.

Respectfully submitted,

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